COUNTY OF LOS ANGELES
Public Health

JONATHAN E. FIELDING, M.D., M.P.H.
Director and Health Officer

JOHN F. SCHUNHOFF, Ph.D.
Chief Deputy Director

313 North Figueroa Street, Room 806
Los Angeles, California 90012
TEL (213) 240-8117 • FAX (213) 975-1273

www.lapublichealth.org

July 31, 2007

TO: Each Supervisor

FROM: Jonathan E. Fielding, M.D., M.P.H. jfielding
Director and Health Officer

SUBJECT: **RADIOACTIVE MATERIALS INSPECTION AT KING-HARBOR**

The Department of Public Health's Radiation Management unit, part of Environmental Health, conducts inspections under contract with the California Department of Public Health.

Radiation Management staff conducted an inspection of radiation safety at King-Harbor from July 17 – 19, 2007. The attached letter and Notice of Violation was sent to King-Harbor yesterday. A compliance conference has been scheduled for August 16, 2007.

We have discussed this with the Director of Health Services and our Deputy Chief Executive Officer.

If you have any questions or need additional information, please let me know.

JEF:js

Attachments

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors
Director of Health Services
Deputy Chief Executive Officer

COUNTY OF LOS ANGELES
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JONATHAN E. FIELDING, M.D., M.P.H.
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JOHN F. SCHUNHOFF, Ph.D.
Chief Deputy Director

Environmental Health
TERRANCE POWELL, R.E.H.S.
Acting Director of Environmental Health

Radiation Management
3530 Wilshire Boulevard, 9th Floor
Los Angeles, California 90010
TEL (213) 351-7897 FAX (213) 351-2718
www.lapublichealth.org/eh/progs/envirp/ehrad.htm

July 30, 2007

Martin Luther King Jr. – Harbor Hospital
12021 South Wilmington Avenue
Los Angeles, CA 90059

Sent by Certified Mail

Attention: Antionette Smith Epps, Administrator

INSPECTION OF CALIFORNIA RADIOACTIVE MATERIALS LICENSE NUMBER 2317-19

Dear Ms. Epps:

On July 17 through 19, 2007, this office conducted an inspection of your facilities and operations as they relate to radiation safety, compliance with the California Code of Regulations, title 17, and the conditions of your Radioactive Materials License. As a result of the inspection we have enclosed a "Notice of Violation" (Notice), which details the items of noncompliance. The items of noncompliance were discussed with Rhonda Bean, Assistant Administrator; Vaughn Payne, Jr., M.D., Interim Chairman, Department of Radiology; Shahram Bonyadlou, M.D., Director, Nuclear Medicine; K. Shanaz Syed, M.D., Radiation Oncologist; and Willie Smoot, CRT, Interim Chief Radiologic Technologist, at the time of our visit and require your written response within 35 days. The Notice requires that you respond to each violation with:

1. The corrective actions which have been taken by you, and the results achieved;

2. The corrective actions taken to avoid similar violations in the future; and,

3. The date when full compliance was or will be achieved.

Due to the number of noncompliances, a compliance conference has been scheduled on August 16, 2007 at 9:30 a.m. at our office located at 3530 Wilshire Boulevard, 9th Floor, Los Angeles, California 90010. The purpose of this conference is to provide you with an opportunity to show cause why the Department should not proceed under Health and Safety Code, sections 115215 Violations; Misdemeanor; Penalties, 115220 Civil Penalties; Violations of this Chapter, Cumulative Remedies. Failure to appear may be deemed cause for further legal action.

Items of Concern

The following items of concern are provided to clarify a violation or in the interest of improving the radiation safety program:

1. With regard to Violation A, Martin Luther King Jr. – Harbor Hospital (King – Harbor) did not have a Radiation Safety Officer (RSO) from January 2007 through July 19, 2007. It was noted during the inspection that Jeffery Hall, M.S., RSO, left the facility in January 2007. Your facility did not realize that you did not have an RSO until Dr. Bonyadlou inquired in March 2007 when he was appointed Director of Nuclear Medicine. During the inspection, Dr. Bonyadlou gave this office a copy of a letter from Mr. Hall that was an amendment request dated May 7, 2007 requesting Dr. Bonyadlou be named as RSO, and Gail Nalls, M.D. as Alternate Radiation Safety Officer (ARSO.) On July 13, 2007, after this office had called King-Harbor asking for the RSO, Dr. Bonyadlou contacted Gonzalo Perez, Sr. Health Physicist, Medical Licensing, Radiologic Health Branch, in Sacramento and inquired about Mr. Hall's letter. Mr. Perez told Dr. Bonyadlou that the letter was never received by Medical Licensing. Mr. Perez also instructed Dr. Bonyadlou to fax another amendment request signed by the hospital's administrator. Dr. Bonyadlou faxed the request to Mr. Perez on July 17, 2007 with the following requests:

    a. Appoint Dr. Bonyadlou as RSO and Radiation Safety Committee (RSC) Chairperson
    b. Appoint Dr. Nalls as ARSO
    c. Change the licensee name from King - Drew Medical Center to Martin Luther King Jr. – Harbor Hospital
    d. Add Dan York (a consultant) as an authorized user (AU) for physical measurements.

    The amended license (#66) was faxed to Dr. Bonyadlou on July 18, 2007. **In your response, you must describe how you will assure future compliance.**

2. With respect to Violation B, King – Harbor did not have a Chairperson for the Radiation Safety Committee from January 2007 to July 18, 2007. Although your radioactive materials license has been amended adding Dr. Bonyadlou as the RSC Chairperson, **you must provide a further response of how you'll assure future compliance**.

3. With regard to Violations C, D, and E, on July 13, 2007, we were informed by Downey Area Recycling and Transfer Facility (DART) that they had received a roll-off bin from King - Harbor that activated their radiation alarm. Stephen Doerfler, Health Physicist, Los Angeles County Radiation Management, contacted the Radiation Safety Office to speak with the RSO. Mr. Doerfler was informed that Jeffery Hall, RSO, was no longer employed by King – Harbor. Mr. Doerfler then spoke with the Nuclear Medicine receptionist who confirmed that Mr. Hall was no longer employed at the facility and told Mr. Doerfler that Vanessa Williams, Radiation Protection Specialist, had assumed some of Mr. Hall's duties. Mr. Doerfler was transferred to Ms. Williams' line and left a voicemail message for Ms. Williams to call him back. When Ms. Williams returned Mr. Doerfler's call, Mr. Doerfler informed her of the incident. During that conversation, Ms. Williams confirmed that Mr. Hall was no longer working at King – Harbor. Mr. Doerfler also informed Ms. Williams that this office would require that the facility investigate the cause for the release of the radioactive material and report the findings to this office. Ms. Williams was instructed by Mr. Doerfler to contact him prior to going to DART for further instructions, including the possible issuance of a Department of Transportation (DOT) exemption by this office, to allow transport of radioactive material on public roads.

   Mr. Doerfler was contacted by a representative from DART on July 13, 2007, informing him that Ms. Williams was already at the transfer station. An employee of DART assisted Ms. Williams in isolating the radioactive waste. Patient information was found with a radioactive diaper in the same bag. (Note that the patient information found may be a Health Insurance Portability and Privacy Act (HIPPA) issue.) This information assisted in confirming that the contaminated diaper came from a patient in the Intensive Care Unit (ICU) that had a HIDA scintigraphy on July 12, 2007. Ms. Williams left DART prior to contacting Mr. Doerfler for transportation instructions, and therefore her transport was a violation of DOT regulations. The July 18, 2007 report faxed to this office on July 18, 2007 addresses the waste release violations. **In your response, you must describe how you will assure future compliance, including compliance with DOT requirements.**

4. With regard to Violation F, a review of the weekly wipe test reports indicates that the test was not properly performed. Wipe tests reveal the presence of removable contamination and are measured in disintegrations per minute (dpm). However, the results on the reports were measured in millirem per hour (mr/hr). During Mr. York's June 12, 2007 evaluation survey, he wrote instructions for wipe testing and generated a form to be used, including the formula for converting counts per minute (cpm) to dpm. Mario Henriquez, CNMT, is the technologist assigned to perform the weekly wipe tests. According to Mr. Henriquez, he never received any training on proper procedures to perform the test. He also said that he did not know how to convert cpm to dpm nor use the well counter, the instrument your facility committed to use for this test, and the more

appropriate instrument for counting wipes. Note that our 2003 letter discussed the issue of using an appropriate instrument for different purposes, and recommended that effectiveness of training be evaluated by interviewing staff and observing procedures.

On July 20, 2007, Mr. York provided training on the performance of the required quality control tests to all nuclear medicine technologists. **In your response, you must describe how you will assure future compliance.**

5. Regarding Violations G, H and I, the daily dose calibrator constancy test, weekly wipes, and daily surveys were not done when the technologists assigned to perform those duties were temporarily re-assigned to other areas or off-duty. For example, during the period of March 2004 through March 2005, the daily constancy test was not done. During a conversation with Edna De Los Angeles, CNMT, she stated that this duty was assigned to the CNMT running the Hot Lab. Ms. De Los Angeles is usually the person running the Hot Lab. However, during the above period, Ms. De Los Angeles was re-assigned to work in the patient care area. The other CNMT assigned to perform the Hot Lab duties did not perform the daily constancy test and daily surveys. The tests were not performed again the whole month of August 2005 through September 18, 2005 when Ms. De Los Angeles was on vacation. In addition, the required weekly wipe tests were not done from June 22, 2007 through our inspection on July 19, 2007 when Mr. Henriquez was out on medical leave. We strongly recommend that your corrective and preventive actions for these violations include a commitment to provide cross training to all the nuclear medicine technologists so they can perform the required tests when the person assigned to perform quality control tests and surveys is not available.

6. With respect to Violation J, the weekly camera resolution test was not performed on the ADAC Room gamma cameras from February 1 through May 31, 2007, and from February 1 through March 31, 2007 on the IRIX Room gamma cameras. When discussed with the CNMT assigned these duties, he indicated that the activity on the cobalt 57 flood source was low and therefore it took too long to perform the test. The test was taking almost 3 hours on 5 camera heads, when it should have taken about 45 minutes. Dr. Bonyadlou stated during the exit conference that you are in the process of ordering a new flood source.

7. With regard to Violation N, your iodine 131 inpatient therapy procedures state that before the patient's room is reassigned to another patient, the room will be surveyed for contamination and decontaminated if necessary. The room will be considered clean if contamination is less than 200 dpm/100 cm^2. There is no indication on the inpatient iodine 131 patient records reviewed during the inspection that contamination surveys were performed prior to releasing the room. The only surveys found in the patient records are the exposure surveys measured from the patient. When Ms. Williams was asked if contamination surveys were done, she stated that only the radiation from the patient is measured, using an ion chamber, an instrument which is not appropriate for performing contamination surveys.

The issue of concern is the potential radiation dose to persons who entered the room after the patient had been released, in particular those cleaning the room & patients who subsequently occupied the room. This issue of potential public doses must be evaluated by a person with adequate health physics experience & expertise in performing these kinds of assessments, and you must provide a report to this office of these potential doses.

8. With regard to Violation P, the cesium brachytherapy sources shipped to your facility in September 2004 were not leak tested until July 2005. The cesium 137 brachytherapy source certificates faxed to this office by the manufacturer state that the sources were leak tested by the manufacturer on September 24, 2004 and therefore, the next leak test was due in March 2005.

9. With regard to Violation Q, one cesium 137 brachytherapy source received in September 2004 was sent back to the manufacturer and was replaced with another source that was shipped to King – Harbor in December 2004. There was no documentation available regarding the transfer of the original source. Because of King-Harbor's failure to have the required records, there was some confusion during the inspection as to whether your facility had exceeded your licensed possession limit or whether a source had been lost. With the assistance of the manufacturer, we were able to obtain information that a cesium 137 brachytherapy source was sent back to the manufacturer for replacement.

10. With regard to Violation R, there were no records available demonstrating that the waste containers were surveyed prior to disposal as regular waste. Your waste disposal log only states the date of disposal. The log must be revised to include the dates when the containers were closed, the container survey results, and date of disposal.

11. It was noted during the inspection that the Xetex waste monitor alarm was set too high. Background was 10 kcpm and the alarm was set to activate at 220 kcpm (22 x10.) Alarms are normally set at 2-3 times background, or in this case 20-30 kcpm. This was an item of concern in our 2003 letter from the last inspection, and this high alarm level is one cause of the DART's alarm. Mr. York adjusted the alarm trigger level to 20 kcpm during the inspection.

12. A review of the personnel monitoring records revealed that the personnel monitoring devices are not returned to the vendor in a timely manner. For example, on the May 6, 2005 report date, the personnel monitoring devices evaluated were the devices for the period of February 15 through March 14, 2005. Monitoring devices for periods April 15 through May 14, 2004, and December 15, 2004 through January 14, 2005 were also included in the May 6, 2005 report. Personnel monitoring devices must be returned to the vendor in a timely manner in order to identify exposures that may require immediate attention.

The cooperation of Martin Luther King, Jr. – Harbor Hospital's staff during the inspection is appreciated. If you have any questions on this or other matters of radiation safety, please contact our office at (213) 351-7378.

Very truly yours,

Joji D. Ortego
Sr. Radiation Protection Specialist

Approved by: _____
Kathleen A. Kaufman, Director
Radiation Management

Enclosure: RH 1019

C: Shahram Bonyadlou, M.D., Radiation Safety Officer
Vaughn Payne, Jr., M.D., Interim Director of Radiology
Rhonda Bean, Assistant Administrator

NOTICE OF VIOLATION
POSTING REQUIRED *

This inspection was an examination of your activities for the purposes of determining whether or not there is compliance with or violation of the provisions of the Radiologic Technology Act [Health & Safety Code § 27(f)], Radiation Control Law [Health and Safety Code § 114960 et seq.], and/or Nuclear Technology Statutes [Health & Safety Code section 107150 et seq.] and/or the rules and regulations promulgated there under [California Code Regulations, title 17, section 30100 et seq.].

EMPLOYER'S NAME	INSPECTION AGENCY
Martin Luther King Jr. – Harbor Hospital	Los Angeles County Department of Public Health Radiation Management 3530 Wilshire Boulevard, 9th Floor Los Angeles, CA 90010 (213) 351-7897
LICENSE NUMBER 2317-19	Attn: Joji D. Ortego, Sr. RPS (213) 351-7378
SITE(S) INSPECTED 12021 South Wilmington Avenue, Los Angeles, CA 90059	**DATE(S) OF INSPECTION** July 17-19, 2007

INSPECTION FINDING(S)/VIOLATION(S): RESPONSE MUST BE WITHIN 35 DAYS

A. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 14 names the individual approved to perform the duties of the Radiation Safety Officer.**

Additionally, the California Code of Regulations, title 17, section 30195, states in part, that for human use of radioactive material in institutions, the institution has a radiation safety officer, who is a member of the radiation safety committee, and who is qualified by reason of training and experience to oversee the radiation safety aspects of radioactive material use in the institution.

Contrary to the above, the named individual left King – Harbor Hospital in January 2007. Therefore, King-Harbor Hospital did not have a Radiation Safety Officer from January 2007 through July 18, 2007.

(continued)

B. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 14 names the individual approved to perform the duties of the Radiation Safety Committee Chairperson.**

Contrary to the above, King – Harbor Hospital did not have an approved Radiation Safety Committee Chairperson from January 2007 through July 18, 2007.

C. **The California Code of Regulations, title 17, section 30253, incorporates by reference title 10, part 20 of the Code of Federal Regulations, section 2001 (10 CFR 20.2001). Section 20.2001 describes the authorized methods of disposal of radioactive material. Disposal through a landfill is not an approved method.**

Contrary to the above, a roll-off bin originating from King – Harbor Hospital was found to contain radioactive material (technetium 99m) when it arrived at Downey Area Recycling and Transfer Station.

D. **The California Code of Regulations, title 17, section 30253, incorporates by reference title 10, part 20 of the Code of Federal Regulations, section 1501 (10 CFR 20.1501). Section 20.1501 requires that each licensee make or cause to be made surveys that evaluate the extent of radiation levels, concentrations or quantities of radioactive material, and the potential hazards that could be present.**

Contrary to the above, King – Harbor Hospital allowed radioactive waste to leave their facility without having been screened for the presence of radioactive material. As a consequence, the radioactive material was sent to the transfer station.

E. **The California Code of Regulations, title 17, section 30373, requires, in part, compliance with the Code of Federal Regulations, 10 CFR, part 71 insofar as such regulations relate to the packaging of radioactive material, marking and labeling of the packages, and loading and storage of packages.**

Contrary to the above, radioactive material was transported without regard for Department of Transportation regulations. Specifically, there was no required marking or labeling of the package, and no shipping papers.

F. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License *Condition 13, with respect to the license application, requires that individuals who work with* radioactive materials or work in the vicinity of areas where radioactive material is used or stored will be instructed in the items specified in the regulations at the time of initial employment, whenever significant changes occur in duties, and at least annually.**

Contrary to the above, there were no records available for review indicating that the nuclear medicine technologists were given instructions on the performance of the required facility surveys at the time of initial employment, or at least annually thereafter.

(continued)

G. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires that all preparation and injection areas be surveyed each day of use with a low-range survey meter for contamination and decontaminated if necessary.**

Contrary to the above, daily surveys were not performed from March 2004 through March 2005, and again from August 2005 through September 18, 2005.

H. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires all laboratory areas (not required to be surveyed daily) to be surveyed weekly, which will consist of measurement of radiation levels with a survey meter and a series of wipe tests.**

Contrary to the above, the weekly wipe tests were not performed during the weeks of June 25, 2007, July 2, and July 9, 2007.

I. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, states that the daily constancy test for the dose calibrator shall be performed each day prior to performing nuclear medicine examinations.**

Contrary to the above, the daily constancy test was not performed prior to performing nuclear medicine studies from March 2004 through March 2005, and again from August 2005 through September 18, 2005.

J. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires that a resolution test on the gamma cameras be performed weekly.**

Contrary to the above, the weekly resolution tests were not performed on the ADAC Room gamma cameras from February 1 through May 31, 2007, and from February 1 through March 31, 2007 on the IRIX room gamma cameras.

K. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires that the dose calibrator linearity test be performed quarterly.**

Contrary to the above, the dose calibrator linearity test was not performed at the proper frequency. There was a 6-month interval between the tests performed on June 2006 and December 2006 and 4-month interval between the tests performed on February 2006 and June 2006 and again on December 2006 and April 2007.

(continued)

L. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires that the dose calibrator accuracy test be performed annually.**

Contrary to the above, the accuracy test was not performed at the proper frequency. There was a 16-month interval between the tests done on February 2006 and June 2007.

M. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, requires the RSO to perform an annual review of the radiation safety program, quarterly review of occupational exposures and quarterly review of records of radiation surveys.**

Additionally, the California Code of Regulations, title 17, section 30253, references the Code of Federal Regulations, title 10, part 20, section 1101 (10 CFR 20.1101), which requires the licensee to periodically (at least annually) review the radiation protection program content and implementation. Section 20.2102 requires the licensee to maintain records of the annual review.

Contrary to the above, the RSO did not perform an annual review of the radiation safety program, quarterly review of occupational exposures, nor quarterly review of records of radiation surveys as required for the year 2006.

N. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, states that prior to releasing the inpatient iodine 131 therapy room, the room will be surveyed for contamination and decontaminated if necessary.**

Additionally, the California Code of Regulations, title 17, section 30253, incorporates by reference title 10, part 20 of the Code of Federal Regulations, section 1501 (10 CFR 20.1501). Section 20.1501 requires that each licensee make or cause to be made surveys that evaluate the extent of radiation levels, concentrations or quantities of radioactive material, and the potential hazards that could be present.

Contrary to the above, there is no evidence that contamination surveys were performed in the patients' rooms prior to release.

(continued)

O. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, states that following arrival and verification of shipping papers of packages containing radioactive materials, radiation surveys must be performed as soon as possible.**

Additionally, the California Code of Regulations, title 17, section 30253, references the Code of Federal Regulations, title 10, part 20, section 1906(b) (10 CFR 20.1906) which states, in part, that each licensee shall monitor the surfaces of a labeled package for radioactive contamination unless the package contains only radioactive material in the form of gas or in special form as defined in 10 CFR 71.4.

Contrary to the above, there were no records available indicating that radiation surveys were performed on the cesium 137 brachytherapy sources shipped to your facility in September 2004 and the cobalt 57 sources shipped to your facility in July 2006.

P. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 15, with respect to the license application, requires that sealed sources possessed under this license be tested for leakage and/or contamination as required by the California Code of Regulations, title 17, section 30275(c).**

Additionally, the California Code of Regulations, title 17, section 30275 (c), states that each sealed source shall be tested for contamination prior to initial use and for leakage at least every six months.

Contrary to the above, the cesium 137 brachytherapy sources shipped to your facility in September 2004 were not leak tested for contamination until July 2005.

Q. **The California Health and Safety Code, section 115105 states that the department shall require each person who acquires, possesses or uses a source of ionizing radiation to maintain records relating to its receipt, storage, transfer or disposal, and other records as the department may require, subject to exemptions as may be provided by regulations.**

Contrary to the above, there were no transfer documents available to review for a cesium 137 brachytherapy source returned to the manufacturer.

R. **The California Code of Regulations, title 17, section 30194, requires licensees to restrict possession of licensed material to the conditions of use authorized in the license. License Condition 13, with respect to the license application, states that waste will be held for decay until radiation levels, as measured with a low-level survey meter and with all shielding removed, have reached levels not statistically significant as compared with background levels.**

Contrary to the above, there were no records indicating that the radioactive waste containers were routinely surveyed prior to disposal as regular trash.

HOW TO RESPOND

If this notice references a violation(s) that was corrected during the inspection, no response is required for that item. For all other violation(s), it will be necessary for you to respond within 35 days from receipt of this notice. The written statement or explanation in reply must include: (a) corrective actions which have been taken by you, and the results achieved; (b) copies of any pertinent service/repair orders; (c) corrective actions which will be taken to avoid further violations; and (d) the date when full compliance will be achieved. Send your response to the Inspection Agency listed above.

Date: July 30, 2007	For the State Department of Public Health
_____	_____
By: Joji D. Ortego, Sr. Radiation Protection Specialist	Approved by: Kathleen A. Kaufman, Director

* Copies of this notice must be conspicuously posted within two working days after receipt. The employer's response shall be posted within two working days after dispatch by the employer. These documents shall remain posted for a minimum of five working days or until action correcting the violation(s) has been completed, whichever is later. Posting shall appear in a sufficient number of places to permit individuals to observe them on the way to or from any particular work location to which this notice is applicable. (California Code Regulations, title 17, section 30255(b)(4), (5))